REMARKS

The continued examination of the current application is respectfully requested pursuant to 37 C.F.R. § 1.114 **(RCE)**. Pursuant to this continued examination, it is respectfully requested that the above amendments be considered in view of the following remarks, and that all claims pending in this application be allowed. Applicants thank the Examiner for discussing the present case with Applicants' representative.

Claims 11-20, 22, 23, and 26-28 are currently pending. New method claims 41-56, corresponding to canceled composition claims 5, 8, 21, 24, 25, and 30-40, have been added herein. Applicants note that all pending claims are now directed to methods, and correspond to composition claims as-filed. Thus, no prohibited new matter has been introduced by this Amendment. Applicants reserve the right to pursue in a division or continuation application any subject matter canceled by way of this Amendment without prejudice or disclaimer.

In the Advisory Action of March 17, 2003, the Examiner did not provide specific remarks addressing each of the specific outstanding rejections. Thus, Applicants provide the following comments in complete response.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph as being purportedly indefinite. Specifically, claim 30 stands rejected for the recitation of the phrase "type" because it is purportedly unclear as to what is meant by "acrylic or acrylamide

type". Claim 30 has been canceled by way of the previous Amendment. Thus, Applicants submit that this rejection is mooted.

Rejections Under 35 U.S.C. §§ 102 and 103(a)

Claims 1-5, 8-14, 17 and 22-25, 30 and 33-38 stood rejected under 35 U.S.C. § 102(e) as being anticipated by Farinas *et al.* (U.S. Patent No. 5,906,830). In complete response to the Advisory Action of March 17, 2003, Applicants note that claims 1-10, 21, 24-25 and 29-40 were canceled by way of the previous Amendment of February 28, 2003, or amended to depend off of claim 26, which was not rejected under 35 U.S.C. § 102. Thus, Applicants submit that the rejection is mooted.

Claims 1-7, 22-28, 30 and 33-35 remain rejected under 35 U.S.C. § 103 as purportedly unpatentable over Farinas *et al.* (U.S. Patent No. 5,906,830). Farinas *et al.* is cited for purportedly disclosing a method for preparing transthermal drug delivery systems containing super saturated drug reservoirs. Farinas *et al.* also purportedly disclose that an amount of drug molecules dispersed in the reservoir material at a concentration that is greater than the solubility of the drug in the reservoir material at a room temperature to give a supersaturated drug reservoir. Again Applicants note that claims 1-10, 21, 24-25 and 29-40 were canceled by way of the previous Amendment and claims 11-20, 22-23 and 28 have been amended to depend off of method claims 26 and 27.

To make a *prima facie* case of obviousness, the Federal Circuit has articulated the analysis of a proper analysis under 35 U.S.C. § 103 as follows:

> [W]here claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *See In re* Dow Chemical Co., . . . 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.

In re Vaeck, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). It respectfully is submitted that a legally sufficient *prima facie* case of obviousness has not been adduced, because the cited art of Farinas *et al.* does not suggest the methods of arriving at a supersaturated state, as presently claimed, let alone suggest that the claimed methods could be conducted with a reasonable expectation of success.

Applicants submit that the skilled artisan would not be motivated to prepare a supersaturated drug delivery reservoir according to the method disclosed in Farinas *et al.* to arrive at the claimed invention. The method of Farinas *et al.* is based on the use of heat to create supersaturation. In contrast, the present claims are directed to a method of creating stable, supersaturated compositions by subjecting the starting materials to chemical operations which result in a matrix capable of maintaining supersaturation. The active ingredient of the present invention is present during the operations, and the solubility of the drug decreases during the chemical operations. This element is what causes the supersaturation. Farinas *et al.* fail to disclose or even suggest this. Further, the products

that result from the processes disclosed by Farinas *et al.* are not the same as the claimed compositions of the present invention. In the case of the present claims, the melting point depression is not utilized using polymeric mixtures. Thus, the skilled artisan would not have an expectation of success at using the methods of Farinas *et al.* to arrive at the present invention.

Thus, the reference does not render obvious the invention as claimed. Accordingly, Applicants respectfully request the appropriate withdrawal of the rejection.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Respectfully submitted,

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Date: April 22, 2003